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September 3, 1999

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Ms. Debbie Lumpkins
Office of Over-the-Counter Drug Evaluation (HFD-560)
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Blvd
Building CRP2, Room S243
Rockville, MD 20850

Attention: Dockets Management Branch (HFA-305)
Food and Drug Administration, Room 1-23
12420 Parklawn Dr.
Rockville, MD 20857

RE: Docket 75N-183H
Topical Antimicrobial Drug Products for Over-the-Counter Human Use;
Tentative Final Monograph for Health-Care Antiseptic Drug Products.
59(116)Federal Register 31402-31452, June 14, 1994.

Dear Ms. Lumpkins:

Please incorporate the following comment into the previous submission of June 15, 1995 by STERIS Corporation, formerly ConvaTec, in regard to the publication of the TFM for Healthcare Antiseptic Drug Products on June 17, 1994.

In order to ensure that the Healthcare Personnel Handwash products are used in a safe and effective manner, STERIS Corporation would like to request changes to the labeling options for the no-rinse product dosage form. It is recommended that the FDA allow product directions to reflect clinical testing results for efficacy of Healthcare Personnel Handwash products in 333.470(b)(2). STERIS would recommend that the direction language be amended to include:

2. For products to be used without water. "Apply a palmful (amount used in clinical testing i.e. 2 - 3 grams) of product to hands and forearms. Rub vigorously into skin until dry. Repeat as necessary."

If you have any questions regarding this submission, please feel free to contact me at (800)243-5799 extension 2276.

Best regards,

Kimberly Adams
Kimberly Adams

STERIS Corporation
St. Louis Operations
Regulatory Affairs

75N-183H

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